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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,275	10/26/2001	Timo Kars van den Berg	080743-235-001	5284

7590 06/02/2004

Ronald A. Sandler
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Chicago, IL 60540

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,275	BERG ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: van den Berg *et al*
Priority Date: 28 April 2000

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/2004 has been entered.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

2. The rejection of claim 8 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant's arguments are substantially similar to those already presented in a paper submitted 6/30/2003. It is noted that applicant maintains the assertion that a deposit of the specific antibodies are not required because they have been fully disclosed in the specification at paragraph [0024]. However, this specific disclosure is not sufficient to support the requirements under the Budapest Treaty. Because the recited antibodies are specifically recited as being part of the claimed invention, it is necessary a required part of the invention. Therefore, applicants must make available to the public all parts of the invention without restriction. Moreover, the incorporation of essential material in the specification by reference to the Damoiseaux *et al* (J. Leukocyte Biol. 1989; 46:556-564) publication is

improper. Applicant is required to amend the disclosure to include the material incorporated by reference (i.e. the antibodies of ED9 and ED17). The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

3. The rejection of claims 1 and 8 under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant's arguments are substantially similar to those already presented in a paper filed 6/30/2003. It is noted that applicant reasserts that in vitro experimentation is predictive of in vivo application, and further cites several published articles to support said assertion. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As stated in the prior office action, because the art teaches that cancer treatment in general is an unpredictable field, the claims drawn to a method of treating cancer, more specifically leukemia, in the absence of guidance would be rather difficult to treat. This unpredictability in the treatment of cancer underscores the importance of working examples in the specification so that one of skill in the art would be able to practice the invention commensurate in scope to the claims without undue

experimentation. Because the current specification is devoid of any in vivo experimentation or any art accepted in vitro models that are predictive of the treatment of leukemia, one of skill in the art would not be able to reasonably predict the effects of in vivo administration of the anti-SIRP antibodies for the treatment of leukemia without undergoing undue experimentation. The references cited by the applicant (of which were not provided in the response filed 3/5/2004) to support the predictability of in vitro findings to in vivo applicability are noted, but do not provide any further incite into whether the use of the anti-SIRP antibodies would be effective in vivo, especially for the treatment of leukemia. It is also noted that all of the references cited by the applicant provide in vivo experimentation in the form of animal models predictive of specific diseases, as such these references fail to support the arguments set forth by the applicant.

Applicant further argues that the moral standards set forth in Europe with regard to animal model testing precludes the applicants from providing animal testing except for in special cases. Applicant's arguments are noted but are not deemed persuasive to overcome the rejection. The role of the Patent Office is to apply the laws that were set forth by Congress to determine the patentability of an invention, and in so doing, there must be a reasonable correlation between what is claimed and what is taught in the specification. Because the treatment of diseases are often difficult to predict solely from in vitro experiments due to factors such as cell-cell contacts and the evolution of cell lines (see Dermer *et al*; previously cited), the testing of treatments is often more suitable in *in vivo* animal models. It is not the role of the Office to comment or determine the

morale standards of animal testing in Europe, but rather to apply the law as set forth by Congress.

Applicant further argues "it is not necessary for all *Wands* factors be reviewed to find a disclosure enabling. The factors are illustrative, not mandatory." Applicant further argues that the lack of in vivo working examples alone is not sufficient to show a lack of enablement. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As stated above, a reasonable correlation between what is claimed and what is taught in the specification must be present for one of skill in the art to practice the invention without undue experimentation. Because the field of cancer or cancer treatment is rather unpredictable as underscored by Gura, in the absence of proper guidance one of skill in the art cannot reasonably predict the outcomes for the administration of anti-SIRP antibodies to an individual. There is not evidence that the administration will "inhibit" a cellular function as claimed. Therefore one of skill cannot predict from the specification as originally filed that the artisan can practice within the scope of the claims.

And finally, applicant argues that other US Patent's have issued without in vivo data present, wherein some experimentation would be necessary. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The prosecution of this case has no bearing on the outcome on any other application, because the instant case is examined on its own merits. There are other situations or circumstances (i.e. the filing of affidavits or declarations) that may

have provided further evidence or support for those cases that may have favored the approval of the application for a patent.

It is further noted that Seiffert *et al* (Blood 1999 December; 94(11):3633-3643) indicates that not all leukemia's express SIRP to the extent that it can be used as target for the treatment of leukemia because only 56% of AML (acute myeloid leukemia) tested expressed SIRP, while no CML (chronic myeloid leukemia) tested expressed SIRP (see pages 3636). Seiffert *et al* go on to further state that the leukemia cells have "aberrant regulation of SIRP expression" (see page 3638). The unpredictable expression of SIRP in leukemic cells underscores the importance of in vivo working examples for specifically targeting SIRP for the treatment of diseases. One of skill in the art would not be able to practice the invention commensurate in scope to the claims without undue experimentation because the art teaches that the leukemic cells have erratic expression of SIRP, and therefore the targeting of SIRP with an anti-SIRP antibody would have an unpredictable outcome. The specification has not set forth any explanation or determination as to how a method of treating leukemia can be accomplished when there is no external expression of the SIRP molecule.

Therefore the rejection under 35 USC 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record.

Conclusion

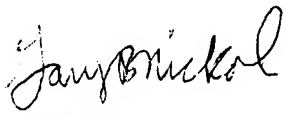
No claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose

telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
May 24, 2004



GARY NICKOL
PRIMARY EXAMINER